STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor

Nancy Wyman
Lt. Governor

Healthcare Quality And Safety Branch

November 5, 2018

Ms. Lucille Janatka, Administrator
Midstate Medical Center
435 Lewis Avenue
Meriden, CT 06450

Dear Ms. Janatka:

Unannounced visits were made to Midstate Medical Center concluding on August 21, 2018 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations and a licensure renewal inspection.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

The plan of correction is to be submitted to the Department by November 19, 2018.

The plan of correction shall include:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;

(2) the date each such corrective measure or change by the institution is effective;

(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and

(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by November 19, 2018 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

An office conference has been scheduled for **December 4, 2018** at **10:00 AM** in the Facility Licensing and Investigations

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Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Susan Newton, R.N., B.S.
Supervising Nurse Consultant
Facility Licensing and Investigations Section

SHN:jf

Complaints #21906, #21031, #22507, #23255, #21625, #23470, #21402, #23432, #22626, #22206, #21316, #22424 and #23743

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The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6)

1. *Based on clinical record review, adverse events, facility policy and staff interview for 1 of 3 sampled patients (Patient #21) reviewed for behaviors, the facility failed to ensure the safety of a patient admitted to the Emergency Department's (ED) behavioral health unit. The findings include:
   a. Patient #20 was admitted to the ED behavioral unit on 11/4/17 for homicidal ideation and schizoaffective disorder. Physician orders dated 11/5/17 directed the patient to be on every fifteen minutes.
   b. Patient #21 was admitted to the ED behavioral unit on 11/1/17. Patient #21's diagnoses included anxiety, Bipolar disorder, major depressive disorder and post-traumatic stress disorder.
   c. Review of facility documentation dated 11/6/17 at 4:15 PM identified that Patient #21 reported to Person #1 that Patient #20 entered their room and began inappropriately touching themselves in front of Patient #21. The documentation identified that Patient #20 was placed on 1 to 1 observational status and was moved to another unit within the hospital and Patient #21 was relocated to a room directly across from the nursing station.

      Interview with RN #9 on 8/13/18 at 10:00 AM stated that the tech who was assigned to every fifteen minute checks on patients was in another patient's room doing vital signs when the incident occurred. RN #9 stated that at the time of the incident if the every fifteen minute checks were completed it was okay for the tech to step off the unit as long as they were back in time for the next check. RN #9 further stated that since the incident any adolescent patient who is admitted is placed in a room visible to the nursing station and if a tech needs to go off the unit, someone else replaces them for patient monitoring. Additionally, RN #9 stated that all staff were re-educated regarding every fifteen minute patient observations.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Services (1) and/or (i) General (6) and/or (l) infection control (1).

2. Based on observations and interviews the facility failed to ensure the glucometer control solution was dated according to facility practice. The findings include:
   a. During tour of the O.R suite and Endoscopy unit it was identified that the Medisense High and Low Glucose Control solution bottles located in the endoscopy unit were dated 10/31/18 for an open date.
      In an interview on 8/13/18 the Manager identified it is standard practice to date the solution bottles upon opening and that the expiration date will be 90 days after opening.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b)

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Administration (2) and/or (e) Nursing Services (1) and/or (i) General (6) and/or (l) infection control (1).

3. Based on observations and interviews the facility failed to ensure that infection control practices were maintained in the Endoscopy suite when staff were observed walking through the endoscope reprocessing area. The findings include:
   a. Observations during tour of the Endoscopy unit on 8/13/18 identified two nurses on separate occasions walking through the endoscope reprocessing area without the benefit of wearing personal protective equipment. On both occasions endoscopes were being washed in the cleaning bay.
   In an interview on 8/13/18 the Manager identified the layout of the endoscopy unit permits staff to walk through the area where endoscopes are being cleaned in order to access other rooms. It is the expectation for the staff to announce their presence if an endoscope is being washed and for the technician to stop the cleaning process. Upon surveyors enquiry the Manager identified staff will be educated and a sign will be posted as a reminder.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff ($) (A) and/or (d) Medical Records (2), and/or (e) Nursing Service (1).

4. Based on clinical record review, interview and policy review the facility failed to ensure that one of six patients reviewed for pain (Patient #26), the hospital failed to ensure the patient's pain was addressed. The findings include the following:
   a. Patient #26 presented to the ED on 9/5/17 with complaints of chest pain/pressure that did not radiate. The patient indicated that s/he had some shortness of breath, nausea, and vomiting since the previous night. The patient had a past medical history inclusive of a DVT, pulmonary embolism, and GERD. The record reflected the patient rated pain as a 6 on a scale of 0-10 (10 being the worst possible pain) at 11:02 AM. The record indicated Morphine 10 mg intravenously was administered at 1:19 PM, more than two hours later. A reassessment of the patient's pain at 1:20 PM noted the patient rated pain as a 5. The record indicated that the patient's pain level was 9 at 3:15 PM and 8 at approximately 6:00 PM prior to discharge however the record failed to reflect that the patient's pain was addressed and/or a rationale for not providing an intervention.
   b. Patient #26 presented to the ED on 9/7/17 at 7:19 AM with complaints of chest pain. The pain was described as epigastric for the past 5 days. The record indicated that the patient had a pain level of 10 on presentation, rated pain as a 3 at 10:07 AM, and was medicated with Tylenol 650 mg orally at 10:30AM. The patient's pain level was reevaluated at 11:22 AM and was a 7, however the record failed to reflect that the patient's pain was addressed and/or a rationale for not providing an intervention. Review of the facility policy indicated that patients who have a pain score greater that zero will be monitored every four hours, patients with a pain level over a 7 will be reported to a provider, and reevaluation of the patients pain score will be assessed 30-60 minutes after parenteral medications.

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The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff ($) (A) and/or (d) Medical Records (2), and/or (e) Nursing Service (1).

5. Based on clinical record review, interview and policy review, for one of three patients reviewed for interventional radiology procedures (Patient #27), the hospital failed to ensure that the physician was notified of elevated blood pressures post-procedure in accordance with the physician's order. The finding includes the following:
   a. Patient #27 was scheduled for a fistulagram in the interventional radiology department on 12/5/17 due to bleeding from the dialysis access site. Review of the pre-procedure orders dated 12/4/17 at 9:30 AM directed that the patient have nothing by mouth after midnight, except for medication and direction to call the MD if the patient's SBP is greater than 140 or less than 90 and DBP greater than 90 or less than 60. On 12/5/17, the patient presented to interventional radiology department. The patient had a past medical history of hypertension, congestive heart failure, end stage renal disease, on hemodialysis, and hyperlipidemia. The patient was noted to be wheelchair dependent. Review of the patient's home medication regimen included Norvasc 5 mg twice daily, aspirin 81 mg daily, Lasix 20 mg daily, Avapro 150 mg daily, and Lopressor 25 mg twice daily.

      Review of the pre-procedure documentation indicated that at 12:15 PM the patient had a BP of 188/71. Review of the record identified that the procedure commenced at 1:23 PM, ended at 1:45 PM and the patient was in recovery at 1:55 PM. Review of the post procedure documentation indicated that at 2:09 PM the patients' blood pressure was 161/64, 170/56 at 2:15 PM, 173/54 at 2:30 PM, 175/67 at 2:45 PM 162/64 at 3:00 PM and 208/67 at 3:30 PM, absent documentation that the physician was notified of the elevated BP in accordance with the physician's order. The record failed to reflect which medications the patient consumed at home, prior to the procedure.

      Review of the procedure note authored by MD #4 dated 12/5/17 identified the patient had a left arm dialysis AV graft with signs of outflow vein stenosis (bleeding after dialysis) and underwent angioplasty of venous stenosis, tolerated the procedure and sedation without any untoward events. Approximately 1.5 hours after the procedure, the patient developed signs of a stroke, a rapid response was called, and s/he was transported to the ED. A head CT was completed on 12/5/17 at 3:55 PM that indicated an acute large intraparenchymal hemorrhage in the right basal ganglia with intraventricular extension. The patient expired on 12/7/17.
      Interview with MD #4 on 8/15/18 at 9:15 AM stated that the patient was stable during the procedure and there were no unusual concerns. MD #4 indicated that he was aware that the

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patient's BP was elevated pre procedure however it normalized during the procedure.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (2), and/or (e) Nursing Service (1).

6. Based on clinical record review, policy review and interview, for one patient reviewed for Clinical Institute Withdrawal Assessment (CIWA) monitoring (Patient #29), the hospital failed to ensure the patient was monitored in accordance with facility policy. The finding includes the following:
    a. Patient #29 was admitted on 8/7/18 with seizures following alcohol withdrawal. Review of the clinical record indicated that the patient was on Clinical Institute Withdrawal Assessment (CIWA) monitoring. Review of the monitoring dated 8/9/18 indicated that at 10:00 AM the patient had a score of 13 which would require hourly assessments in accordance with facility policy. The record reflected that the next assessment was not completed until 12:00 PM, two hours later. A subsequent assessment at 2:00 PM indicated a score of 15 then again at 4:00 PM with a score of 15. The hospital failed to ensure assessments were completed every hour. In addition, review of the monitoring on 8/10/18 during the period of 8:00 PM through 8:00 AM indicated that monitoring was completed every 2 hours although the patient's CIWA score ranged from 8-15. Review of the facility policy indicated that for a CIWA score of 8-15 monitoring should be completed every hour.

The following are violations of the Regulations of Connecticut State of Agencies Section 19-13-D3 Short Term Hospitals, General and Special (a) Physical Plant (2) & (i) General (7).

7. During a tour of MidState Hospital on August 13th and 14th 2018 and subsequent documentation review, the following were observed:

    a. The surveyor, accompanied by the Engineering Compliance Officer, observed that the wall surfaces within Operating Room #8 has peeling paint, bare joint compound, and holes in wall surfaces, not providing the maintenance of a sanitary condition.
    b. The surveyor, accompanied by the Engineering Compliance Officer, observed that the floor surfaces within the Dietary Department Dry Storage Room has holes, missing pieces of flooring and has a significant accumulation of dirt and debris, not providing the maintenance of a sanitary condition.
    c. The surveyor, accompanied by the Engineering Compliance Officer, observed that the facility has installed two (2) portable storage units on the exterior of the facility and are utilizing these units as operational components of the facility without submitting plans to both the local authority having jurisdiction (AHJ) and the Connecticut Department of Public Health.
    d. The facility failed to provide the surveyor with documentation that would indicate that appropriate permits for electrical, HVAC, structural, plumbing, and zoning (if applicable) for the two (2) portable storage units on the exterior of the facility being

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utilized as operational components of the facility, and an approved certificate of occupancy has been issued by the local AHJ as required by section 105.1 of the International Building Code.

Approved 11/20/18 SHN

The filing of this Plan of Correction does not constitute any admissions to any of the alleged violations set forth in this statement of deficiencies. The Plan of Correction is being filed as evidence of the facility's continued compliance with all applicable laws and the facility's desire to continue to provide quality services. The facility requests that this plan of correction be considered as its allegation of substantial compliance.

Findings:	Corrective Measure(s) and Follow-up Measures	Completion Date	Responsible Staff by Title
*1.a-c.	The facility failed to ensure the safety of a patient admitted to the Emergency Department's behavioral health unit. The following plan has been put into place: • Review of the Observation of Patients Policy was conducted by the Director of Behavioral Health with no changes identified. Completed 8/20/2018. • The Observation of Patients Policy was sent to all Acute Behavioral Unit staff, in a read and sign attestation format. Completed • An SBAR (Situation, Background, Assessment and Recommendation) communication regarding Observation Status in the ABU was printed and an attestation read and sign was provided to all staff. Completed Auditing: A random audit of 20 charts per month will be conducted to identify MD order for observation status and RN assessment prior to change in observation status to ensure compliance with policy. Compliance achieved will be 90% or higher for 3 consecutive months.	9/10/2018	Director Behavioral Health
2.a.	The facility failed to ensure in Endoscopy that the glucometer control solution was dated according to facility practice. The following plan has been put into place: • The nurse manager reviewed instructions with the charge nurses responsible for the appropriate labeling of the control solution vials with the 90-day last day of use expiration date. Completed 11/05/2018. Auditing: A weekly audit will be conducted to ensure appropriate labeling of the glucometer control vials with last day of use expiration date. Compliance achieved will be 90% or higher for 3 consecutive months.	11/05/2018	Nurse Manager, Endoscopy
3.a.	The facility failed to ensure that infection control practices were maintained in the Endoscopy suite when staff was observed walking through the endoscope reprocessing area. The following plan had been put into place immediately following survey and staff review repeated: • Signs posted in all back hallway room doors for Conditional 'Do Not Enter' posted. Signage was posted at the back room doors from scope to procedure room side. Completed 11/16/2018. • Staff was reminded at department safety huddle to limit non-essential traffic through soiled reprocessing room and to announce self upon entering the reprocessing room. Completed 11/16/2018. • Physician access into reprocessing room via scope room door was removed with physician communications posted at each physician computer station for awareness. Completed 11/19/18. • Nurse Manager instructed Clinical Care Assistants not to allow staff/provider access to the reprocessing room except for essential staff. Completed 11/19/18. Auditing: Managers and or charge nurse to monitor staff access to reprocessing room daily with real-time feedback to non-compliant staff. Compliance achieved will be 90% or higher for 2 consecutive months beginning	11/19/2018	Nurse Manager, Endoscopy

4.a-b.	The facility failed to ensure that a patient's pain was addressed in the Emergency Department. The following plan has been put into place: • Education was provided to ED nurses regarding pain reassessment documentation requirements via email and expectations reinforced at daily safety huddles. Completed 11/18/18. • All ED RNs were assigned education, Annual Pain Protocol Documentation. Completed 11/18/18. Auditing: ED Nurse Manager or designee to audit 20 patient records per month for appropriate documentation of pain assessment until 90% or better compliance is achieved for 3 consecutive months. Monitoring will include pain assessments documented every 4 hours for pain level greater than zero, provider notification of pain levels over 7, discharge documentation that pain addressed or rationale for not providing intervention, re-evaluation of pain score 30-60 minutes after parenteral pain medication and 60-120 minutes after oral pain medication administration.	11/18/18	Nurse Director, Emergency Nursing

5.n.	The facility failed to ensure that the physician was notified of elevated blood pressures post-procedure in accordance with the physician's order. The following plan has been put into place:
	• An awareness communication was provided to Surgicenter/PACU RNs stating,
	  • The importance and expectation of MD notification when blood pressure reading is out of range per physician's order. Completed 11/16/2018
	  • The expectation that RNs will document provider notification for blood pressures out of range per physician's order. Completed 11/16/2018
	
	Auditing: Monitor 5 (or 100% if less than 5) records per month of Interventional Radiology patients recovering in the PACU for nursing documentation compliance of provider notification for blood pressures post-procedure in accordance with the physician order. Monitoring will continue until 90% or better compliance is achieved for 3 consecutive months.
		11/16/2018	Nurse Manager, Surgicenter and PACU

6.a.	The facility failed to ensure a patient was monitored in accordance with the facility CIWA policy. Clarification: At time of survey, it was determined the patient's nurse was documenting CIWA assessments every two hours which was consistent with the newly revised policy going into effect on 8/18/18, approximately one week after this survey. The patient's nurse had completed the education for the revised CIWA policy regarding frequency of assessments and was documenting to the revised assessment schedule of every two hours per patient scenario. While there was no harm to the patient the following plan was put into place: • Reviewed with department RNs the importance of ensuring frequency of documentation assessments is consistent with the policy in effect. Current policy remains in effect until the effective date of the revised policy.	8/18/18	Nurse Manager, Critical Care
7.a-d.	During a tour of the hospital on August 13 – 14, 2018 and subsequent documentation review the following corrective actions were put in place: a. OR 8 was painted on 8/13/2018. A monthly inspection for damage and or needed painting is conducted by the engineering department for all operating rooms. Initiated 10/01/2018. b. The flooring in question was repaired on 9/16/2018. The Food Services Department Management will report timely identified repairs and/or painting to the Engineering Department. Completed 9/16/2018. c. All appropriate permits have been obtained. CT DPH building Inspector will be notified of all installed trailers, including temporary. Completed 8/24/2018. d. Permits were obtained for temporary trailer heating and electricity. Completed 8/24/2018.	10/01/2018	Manager, Facilities, Engineering and Operations